

SINUS HEADACHE DAY NIGHT- acetaminophen, chlorpheniramine maleate, and phenylephrine hydrochloride
AmeriSource Bergen

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

GNP - 1149 - 2019-1002

SINUS + HEADACHE DAY

Drug Facts

<i>Active ingredients (in each day caplet)</i>	<i>Purpose</i>
Acetaminophen 325 mg	Pain reliever/fever reducer
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold:
 - headache
 - sinus congestion and pressure
 - nasal congestion
 - minor aches and pains
- helps decongest sinus openings and passages
- promotes sinus drainage
- helps clear nasal passages
- temporarily reduces fever

SINUS + HEADACHE NIGHT

Drug Facts

<i>Active ingredients (in each night caplet)</i>	<i>Purpose</i>
Acetaminophen 325 mg	Pain reliever/fever reducer
Chlorpheniramine maleate 2 mg	Antihistamine
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold:
 - headache
 - sinus congestion and pressure

- nasal congestion
- runny nose and sneezing
- minor aches and pains
- helps decongest sinus openings and passages
- promotes sinus drainage
- helps clear nasal passages
- temporarily reduces fever

Warnings

Liver warning

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert

Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- **do not exceed recommended dosage**

In addition, when using Sinus + Headache Night:

- excitability may occur, especially in children

- drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- do not take more than directed (see overdose warning)
- do not take Day and Night caplets at the same time
- do not take more than a total of 10 caplets in 24 hours

adults and children 12 years and over	<ul style="list-style-type: none"> ■ take 2 caplets every 4 hours ■ swallow whole; do not crush, chew, or dissolve
children under 12 years	<ul style="list-style-type: none"> ■ ask a doctor

Other information

- store between 20-25°C (68-77°F) in a dry place
- retain carton for complete product information and warnings

Inactive ingredients

Sinus + Headache Day

acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, D&C yellow #10, FD&C blue #1, flavor, hypromellose, lactose anhydrous, magnesium stearate, povidone, pregelatinized starch, propylene glycol, sodium starch glycolate, stearic acid, titanium dioxide

Sinus + Headache Night

acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, flavor, hypromellose, iron oxide ochre, lactose anhydrous, magnesium stearate, povidone, pregelatinized starch, propylene glycol,

stearic acid, titanium dioxide

PRINCIPAL DISPLAY PANEL

GOOD NEIGHBOR PHARMACY

NDC 46122-413-60

DAY & NIGHT

Sinus + Headache

pain reliever/fever reducer, nasal decongestant, antihistamine*

For Adults

acetaminophen, phenylephrine hcl, chlorpheniramine maleate*

*Antihistamine in Nighttime only

Daytime (Non-Drowsy)

Sinus Headache, Sinus Pressure, Nasal Congestion

COOL TASTE

12 CAPLETS

Nighttime

Sinus Headache, Sinus Pressure, Nasal Congestion, Runny Nose*

COOL TASTE

8 CAPLETS

DAY

DO NOT TAKE THE DAY AND NIGHT CAPLETS AT THE SAME TIME.

DO NOT TAKE MORE THAN A TOTAL OF 10 CAPLETS IN A 24-HOUR PERIOD. TAKE ONLY AS DIRECTED.

NIGHT

Drug Facts	Drug Facts
Active ingredients (in each day caplet) Acetaminophen 325 mg.....Pain reliever/fever reducer Phenylephrine HCl 5 mg.....Nasal decongestant	Active ingredients (in each night caplet) Acetaminophen 325 mg.....Pain reliever/fever reducer Chlorpheniramine maleate 2 mg.....Antihistamine Phenylephrine HCl 5 mg.....Nasal decongestant
Purpose	Purpose
Uses ■ temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold: ■ headache ■ sinus congestion and pressure ■ nasal congestion ■ minor aches and pains ■ helps decongest sinus openings and passages ■ promotes sinus drainage ■ helps clear nasal passages ■ temporarily reduces fever	Uses ■ temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold: ■ headache ■ sinus congestion and pressure ■ nasal congestion ■ minor aches and pains ■ helps decongest sinus openings and passages ■ promotes sinus drainage ■ helps clear nasal passages ■ temporarily reduces fever
Warnings Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. Severe liver damage may occur if you take more than 4,000 mg of acetaminophen in 24 hours. ■ With other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin redness ■ blisters ■ rash If a skin reaction occurs, stop use and seek medical help right away. Do not use ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.	Warnings Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. Severe liver damage may occur if you take more than 4,000 mg of acetaminophen in 24 hours. ■ With other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin redness ■ blisters ■ rash If a skin reaction occurs, stop use and seek medical help right away. Do not use ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

LIFT PANEL FOR MORE DRUG FACTS INFORMATION



Sinus + Headache

pain reliever/fever reducer,
nasal decongestant,
antihistamine*

For Adults - Day & Night



NDC 46122-413-60

DAY & NIGHT

Sinus + Headache

pain reliever/fever reducer, nasal decongestant, antihistamine*

For Adults

acetaminophen, phenylephrine hcl,
chlorpheniramine maleate*

*Antihistamine in Nighttime only

Daytime (Non-Drowsy)

Nighttime

- Sinus Headache
- Sinus Pressure
- Nasal Congestion

- Sinus Headache
- Sinus Pressure
- Nasal Congestion
- Runny Nose*

COOL TASTE
12 CAPLETS



COOL TASTE
8 CAPLETS



Drug Facts (continued)

Inactive ingredients Sinus + Headache Day acetaminophen, colloidal silicon dioxide, croscarmellose sodium, FD&C yellow #10, FD&C blue #1, flavor, hypromellose, lactose anhydrous, magnesium stearate, povidone, pregelatinized starch, propylene glycol, sodium starch glycolate, stearic acid, titanium dioxide
Sinus + Headache Night acetaminophen, colloidal silicon dioxide, croscarmellose sodium, FD&C yellow #10, FD&C blue #1, flavor, hypromellose, lactose anhydrous, magnesium stearate, povidone, pregelatinized starch, propylene glycol, sodium starch glycolate, stearic acid, titanium dioxide

Other information ■ store between 20-25°C (68-77°F) in a dry place
■ retain carton for complete product information and warnings

Directions ■ do not take more than directed (see overdose warning)
■ do not take Day and Night caplets at the same time
■ do not take more than a total of 10 caplets in 24 hours
adults and children ■ take 2 caplets every 4 hours
12 years and over ■ swallow whole – do not crush, chew, or dissolve
children under 12 years ■ ask a doctor

notice any signs or symptoms.
(1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not

DO NOT USE IF BLISTER UNITS
ARE TORN OR BROKEN



SINUS HEADACHE DAY NIGHT

acetaminophen, chlorpheniramine maleate, and phenylephrine hydrochloride kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46 122-413
--------------	----------------	--------------------	----------------

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46 122-413-60	1 in 1 CARTON	03/01/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BLISTER PACK	12
Part 2	1 BLISTER PACK	8

Part 1 of 2

ACETAMINOPHEN, PHENYLEPHRINE HYDROCHLORIDE

acetaminophen and phenylephrine hydrochloride tablet, coated

Product Information				
Route of Administration		ORAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	325 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		PHENYLEPHRINE HYDROCHLORIDE	5 mg	
Inactive Ingredients				
Ingredient Name			Strength	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	green	Score	no score	
Shape	OVAL (capsule-shaped)	Size	17mm	
Flavor	MINT	Imprint Code	AAA;1114	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part341			
Part 2 of 2				

ACETAMINOPHEN, CHLORPHENIRAMINE MALEATE, PHENYLEPHRINE HYDROCHLORIDE				
acetaminophen, chlorpheniramine maleate, and phenylephrine hydrochloride tablet, coated				
Product Information				
Route of Administration		ORAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	325 mg	
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)		CHLORPHENIRAMINE MALEATE	2 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		PHENYLEPHRINE HYDROCHLORIDE	5 mg	
Inactive Ingredients				
Ingredient Name			Strength	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)				
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	white (Off-White)	Score	no score	
Shape	OVAL (capsule-shaped)	Size	17mm	
Flavor	MINT	Imprint Code	AAA;1117	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/01/2018	

Labeler - AmeriSource Bergen (007914906)

Revised: 10/2019

AmeriSource Bergen